



Roche Position on Nanotechnology

Background

BASICS. Nanotechnology is the science of very small particles with a size between approximately 1 and 100 nanometers (1 nm = 10^{-9} m; 1 mm = 1.000.000 nm). Notably, particles of that size tend to attain novel characteristics that have led to nanotechnology being viewed as one of the key technologies of the 21st century.

Conceptually, nanoscience and nanotechnology refer to science and technology at the scale of 10s to 1000s of atoms and molecules, and to the scientific principles and new properties that can be understood and mastered when operating in this domain. It is not seen as a branch of any specific scientific or technological discipline, but rather as cross-disciplinary in nature, encompassing and combining relevant areas of chemical, physical, biological, and information technologies. Nanotechnology is still a new field for scientists to explore, and as such, many unanswered questions remain. The risks and benefits of nanotechnology have to be carefully evaluated, especially if it is to be implemented in medicines or therapies.

APPLICATIONS. While applications of nanotechnology are expected in multiple areas, Roche's interest in nanotechnology is focused on:

- Medicine
 - Nanocomposites as drug delivery systems
 - Regenerative medicine
 - Diagnostics ("lab-on-a-chip");
- Ultra-high strength materials;
- Data storage and retrieval systems that are orders of magnitude bigger and faster than today;
- Catalysts.

Stakeholders' Expectations and Concerns

As in all new fields of science, there are expectations and concerns from various stakeholders in society relating to the research on and the impact of applying nanotechnology. Innovative companies are expected to explore emerging fields of science to find new opportunities and benefits for society. Stakeholders' expectations regarding advantages of promising new technologies, however, are equally closely linked to the requirements for careful evaluation of potential health and safety risks. Concerns relate to safety and possible long term effects on the environment. Neither the properties of nanotechnology nor the possible long term adverse effects of the use of nanotechnology-based new materials, processes and therapies are known by now. At



the same time, the use of nanotechnology offers important innovation and opportunities for scientific progress in the field of healthcare research.

Roche's Position

Roche is aware of the societal and ethical questions, concerns and expectations raised, in particular those related to potential human and environmental safety aspects of nanotechnology. Roche is fully committed to take these questions, concerns and requests seriously and to address them in a professional and socially responsible way.

As an innovation-driven global healthcare leader, Roche aims to improve the quality of human life by providing innovative products and services for prevention, diagnosis and treatment of diseases. Roche's goal is to help alleviate human suffering caused by diseases. Nanotechnology has the potential to play a role in that mission – and nanoscale materials have indeed been used in certain instances for many years in Roche's products in pharmaceuticals and diagnostics (micelles for drugs, polymer particles in diagnostic products).

Roche scientists are aware of the potential use of novel nanomaterials as research tools as well as in therapeutic and diagnostic applications, in particular in the area of innovative drug delivery technology. We are following and generating progress as an innovative company in the field attentively. As with all other new therapeutics, the potential safety risks related to nanotechnology-based therapies must and will be carefully evaluated before any market introduction. Likewise, prior to entering into a partnership in the area of nanotechnology, we will critically and carefully evaluate the specific practices and standards that our potential partners apply.

Roche is of the opinion that the existing, state-of-the-art safety and toxicity assessments by specific laboratory tests to monitor compound-specific absorption, distribution, metabolism and excretion allow appropriate safety evaluation of novel therapies. We believe that the current regulations may well provide an adequate framework for a critical assessment of new nanotechnology based compounds' safety. This needs to be carefully monitored over time.

We encourage further studies and promote informed dialogue about nanotechnology among different stakeholders. It is important to explore the opportunities of this technology cautiously but proactively, neither overstating the possible risks nor overemphasizing the potential benefits. Given the valuable potential of nanotechnology, Roche takes a favorable position towards active, safety-aware research in the field, but opposes any actions that would block the realization of potential benefits of nanotechnology and of generating the requisite safety database. In all our present and future activities in nanotechnology – in pursuit of our ultimate goal and responsibility to serve human health and well-being – we will conduct our activities by taking into account the public concerns and expectations as well as all applicable laws and regulations.



Roche's Engagement

Roche is a founding member of the Nano-Medicines and Nano-Devices Alliance, a consortium of pharmaceutical companies aimed at promoting and facilitating the development, regulatory approval, and public appreciation of nanomedicines and medical nanodevices for the diagnosis, treatment, and prevention of disease, injury, and chronic pain. Roche is committed to continuously report on progress and experiences, positive and negative ones, resulting from its involvement in nanotechnology.

The Roche Science and Ethics Advisory Group (SEAG), a body of external experts from the fields of ethics, law, sociology, and members of the general public advises Roche on a regular basis on issues associated with innovative developments in biomedicine, with particular emphasis on their ethical impact, including nanotechnology. The SEAG has also reviewed this Position Paper.

This position paper was proposed by the Corporate Sustainability Committee and was adopted by the Corporate Executive Committee on May 12, 2009 and entered into force the same day. It was reviewed in April 2012.